

**MICHIGAN DEPARTMENT OF COMMUNITY HEALTH**  
**CERTIFICATE OF NEED (CON) REVIEW STANDARDS**  
**FOR MAGNETIC RESONANCE IMAGING (MRI) SERVICES**

(By authority conferred on the CON Commission by Section 22215 of Act No. 368 of the Public Acts of 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being sections 333.22215, 24.207, and 24.208 of the Michigan Compiled Laws.)

**Section 1. Applicability**

Sec. 1. (1) These standards are requirements for the approval of the initiation, expansion, replacement, relocation, or acquisition of MRI services and the delivery of services for all projects approved and Certificates of Need issued under Part 222 of the Code that involve magnetic resonance imaging services.

(2) Magnetic resonance imaging is a covered clinical service for purposes of Part 222 of the Code. An MRI unit approved pursuant to Section 9(1) seeking approval to operate pursuant to sections 3, 4, 5, 6, 7, or 8 shall be considered as a person requesting CON approval to initiate, expand, replace, relocate, or acquire a covered clinical service, as applicable.

(3) The Department shall use sections 3, 4, 5, 6, 7, 8, 9, 10, 13, 14, 15, 16, and 17 as applicable, in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws.

(4) The Department shall use Section 12, as applicable, in applying Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

**(5) THE DEPARTMENT SHALL USE SECTION 11, AS APPLICABLE, IN APPLYING SECTION 22215(1)(B) OF THE CODE, BEING SECTION 333.22215(1)(B) OF THE MICHIGAN COMPILED LAWS.**

**Section 2. Definitions**

Sec. 2. (1) For purposes of these standards:

(a) "Acquisition of an existing MRI service or **EXISTING MRI unit(s)**" means obtaining control or possession of an existing fixed or mobile MRI service or **EXISTING MRI unit(s)** by contract, ownership, lease, or other comparable arrangement.

(b) "Actual MRI adjusted procedures," for purposes of sections 15 and 16, means the number of MRI procedures, adjusted in accordance with the applicable provisions of Section 13, performed on an existing MRI unit, or if an MRI service has two or more MRI units at the same site, the average number of MRI adjusted procedures performed on each unit, for the 12-month period reported on the most recently published "Available MRI Adjusted Procedures List," as of the date an application is deemed complete by the Department.

(c) "Available MRI adjusted procedures," for purposes of Section 15, means the number of MRI adjusted procedures performed by an existing MRI service in excess of 8,000 per fixed MRI unit and 7,000 per mobile MRI unit. For either a fixed or mobile MRI service, the number of MRI units used to compute available MRI adjusted procedures shall include both existing and approved but not yet operational MRI units. In determining the number of available MRI adjusted procedures, the Department shall use data for the 12-month period reported on the most recently published list of available MRI adjusted procedures as of the date an application is deemed complete by the Department.

In the case of an MRI service that operates, or has a valid CON to operate, more than one fixed MRI unit at the same site, the term means the number of MRI adjusted procedures in excess of 8,000 multiplied by the number of fixed MRI units at the same site. For example, if an MRI service operates, or has a valid CON to operate, two fixed MRI units at the same site, the available number of MRI adjusted procedures is the number that is in excess of 16,000 (8,000 x 2) MRI adjusted procedures.

55 In the case of a mobile MRI unit, the term means the sum of all MRI adjusted procedures performed  
56 by the same mobile MRI unit at all of the host sites combined that is in excess of 7,000. For example, if a  
57

58 mobile MRI unit serves five host sites, the term means the sum of MRI adjusted procedures for all five  
59 host sites combined that is in excess of 7,000 MRI adjusted procedures.

60 (d) "Central service coordinator" means the organizational unit that has operational responsibility  
61 for a mobile MRI unit(s). It shall be a legal entity authorized to do business in the State of Michigan.

62 (e) "Certificate of Need Commission" or "CON Commission" means the Commission created  
63 pursuant to Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.

64 (f) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 et  
65 seq. of the Michigan Compiled Laws.

66 (g) "Contrast MRI procedure" means an MRI procedure involving either of the following: (i) a  
67 procedure following use of a contrast agent or (ii) procedures performed both before and after the use of  
68 a contrast agent.

69 (h) "Dedicated pediatric MRI" means an MRI unit on which at least 80% of the MRI procedures are  
70 performed on patients under 18 years of age

71 (i) "Department" means the Michigan Department of Community Health (MDCH).

72 (j) "Doctor" means an individual licensed under Article 15 of the Code to engage in the practice of  
73 medicine, osteopathic medicine and surgery, chiropractic, dentistry, or podiatry.

74 (k) "Existing magnetic resonance imaging service" or "existing MRI service" means either the  
75 utilization of an ~~authorized~~ **CON-APPROVED AND OPERATIONAL** MRI unit(s) at one site in the case of  
76 a fixed MRI service and in the case of a mobile MRI service, the utilization of an ~~authorized~~ **CON-**  
77 **APPROVED AND OPERATIONAL** mobile MRI unit(s) at each host site, on the date an application is  
78 submitted to the Department.

79 **(L) "EXISTING MAGNETIC RESONANCE IMAGING UNIT" OR "EXISTING MRI UNIT" MEANS A**  
80 **CON-APPROVED AND OPERATIONAL MRI UNIT USED TO PROVIDE MRI SERVICES.**

81 (l) "Expand a ~~an~~ **EXISTING** fixed MRI service" means an increase in the number of fixed MRI units  
82 to be operated by the applicant ~~at the same site.~~

83 (m) "Expand a ~~an~~ **EXISTING** mobile MRI service" means the addition of a mobile MRI unit that will  
84 be operated by a central service coordinator that is approved to operate one or more mobile MRI units as  
85 of the date an application is submitted to the Department.

86 (n) "Group practice," for purposes of Section 16(3)(b), means a group practice as defined pursuant  
87 to the provisions of 42 U.S.C. 1395nn (h)(4), commonly known as Stark II, and the Code of Federal  
88 Regulations, 42 CFR, Part 411, published in the Federal Register on August 14, 1995, or its replacement.

89 (o) "Health service area" or "HSA" means the geographic areas set forth in Section 19.

90 (p) "Host site" means the site at which a mobile MRI unit is authorized by CON to provide MRI  
91 services.

92 (q) "Initiate a fixed MRI service" means begin operation of a fixed MRI service at a site that does  
93 not provide or is not CON approved to provide fixed MRI services as of the date an application is  
94 submitted to the Department. The term does not include the acquisition or relocation of an existing fixed  
95 MRI service or the renewal of a lease.

96 (r) "Initiate a mobile MRI host site" means the provision of MRI services at a host site that has not  
97 received any MRI services within 12 months from the date an application is submitted to the Department.  
98 The term does not include the renewal of a lease.

99 (s) "Initiate a mobile MRI service" means begin operation of a mobile MRI unit that serves two or  
100 more host sites.

101 The term does not include the acquisition of an existing mobile MRI service or the renewal of a  
102 lease.

103 (t) "Inpatient," for purposes of Section 13 of these standards, means an MRI visit involving an  
104 individual who has been admitted to the licensed hospital at the site of the MRI service/unit or in the case  
105 of an MRI unit that is not located at that licensed hospital site, an admitted patient transported from a  
106 licensed hospital site by ambulance to the MRI service.

107 (u) "IRB" or "institutional review board" means an institutional review board as defined by Public  
108 Law 93-348 that is regulated by Title 45 CFR 46.

(v) "Licensed hospital site" means a health facility licensed under Part 215 of the Code. In the case of a single site hospital, it is either (i) the location of the facility authorized by license and listed on that licensee's certificate of licensure or (ii) in the case of a hospital with multiple sites, the location of each separate and distinct inpatient unit of the health facility as authorized by the licensee's certificate of licensure.

(w) "Magnetic resonance" or "MR" means the analysis of the interaction that occurs between radio frequency energy, atomic nuclei, and strong magnetic fields to produce cross sectional images similar to those displayed by computed tomography (CT) but without the use of ionizing radiation.

(x) "Magnetic resonance imaging adjusted procedure" or "MRI adjusted procedure" means an MRI visit, at an existing MRI service, that has been adjusted in accordance with the applicable provisions of Section 13.

(y) "Magnetic resonance imaging database" or "MRI database" means the database, maintained by the Department pursuant to Section 12 of these standards, that collects information about each MRI visit at MRI services located in Michigan.

(z) "Magnetic resonance imaging procedure" or "MRI procedure" means a procedure conducted by an MRI unit approved pursuant to sections 3, 4, 5, 6, 7, 8 or 10 of these standards which is either a single, billable diagnostic magnetic resonance procedure or a procedure conducted by an MRI unit at a site participating with an approved diagnostic radiology residency program, under a research protocol approved by an institutional review board. The capital and operating costs related to the research use are charged to a specific research account and not charged to or collected from third-party payors or patients. The term does not include a procedure conducted by an MRI unit approved pursuant to Section 9(1).

(aa) "Magnetic resonance imaging services" or "MRI services" means either the utilization of an authorized MRI unit(s) at one site in the case of a fixed MRI service or in the case of a mobile MRI service, the utilization of an authorized mobile MRI unit at each host site.

(bb) "Magnetic resonance imaging unit" or "MRI unit" means the magnetic resonance system consisting of an integrated set of machines and related equipment necessary to produce the images and/or spectroscopic quantitative data from scans.

(cc) "Magnetic resonance imaging visit" or "MRI visit" means a single patient visit to an MRI service/unit that may involve one or more MRI procedures.

(dd) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6 and 1396r-8 to 1396v.

(ee) "Metropolitan statistical area county" means a county located in a metropolitan statistical area as that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.

(ff) "Micropolitan statistical area county" means a county located in a micropolitan statistical area as that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.

(gg) "Mobile MRI unit" means an MRI unit operating at two or more host sites and that has a central service coordinator. The mobile MRI unit shall operate under a contractual agreement for the provision of MRI services at each host site on a regularly scheduled basis.

(hh) "Ownership interest, direct or indirect," for purposes of these standards, means a direct ownership relationship between a doctor and an applicant entity or an ownership relationship between a doctor and an entity that has an ownership relationship with an applicant entity.

(ii) "Pediatric patient," for purposes of these standards, except for Section 10, means a patient who is 12 years of age or less.

(jj) "Planning area," for purposes of these standards, means

(i) in the case of a proposed fixed MRI service or unit, the geographic area within a 20-mile radius from the proposed site if the proposed site is not in a rural or micropolitan statistical area county and a 75-mile radius from the proposed site if the proposed site is in a rural or micropolitan statistical area county.

For purposes of Section 7(83) of these standards, the planning area shall be measured from the original

163 site at which the MRI service was first initiated.

164 (ii) in the case of a proposed mobile MRI service or unit, except as provided in subsection (iii), the  
165 geographic area within a 20-mile radius from each proposed host site if the proposed site is not in a rural  
166 or micropolitan statistical area county and within a 75-mile radius from each proposed host site if the  
167 proposed site is in a rural or micropolitan statistical area county.

168 (iii) in the case of a proposed mobile MRI service or unit meeting the requirement of Section  
169 13(2)(d), the health service area in which all the proposed mobile host sites will be located.

170 (kk) "Referring doctor," for purposes of these standards, means the doctor of record who ordered  
171 the MRI procedure(s) and either to whom the primary report of the results of an MRI procedure(s) is sent  
172 or in the case of a teaching facility, the attending doctor who is responsible for the house officer or  
173 resident that requested the MRI procedure.

174 (ll) "Relocate an existing MRI service AND/OR MRI unit(s)" means a change in the location of an  
175 existing MRI service AND/OR MRI unit(s) from the existing site to a different site within the relocation  
176 zone.

177 (mm) "Relocation zone," for purposes of these standards, means the geographic area that is within a  
178 5-mile radius of the existing site of the MRI service or unit to be relocated if the existing MRI service or  
179 unit is not located in a rural or micropolitan statistical area county and a 10-mile radius if OF the existing  
180 SITE OF THE MRI service or unit is TO BE RElocated in a rural or micropolitan statistical area county.

181 (nn) "Renewal of a lease" means extending the effective period of a lease for an existing MRI unit  
182 that does not involve either replacement of the MRI unit, as defined in Section 2(1)(oo)(i), or (ii) a change  
183 in the parties to the lease.

184 (oo) "Replace an EXISTING MRI service or unit" means (i) any equipment change involving a  
185 change in, or replacement of, the magnet resulting in an applicant operating the same number and type  
186 (fixed or mobile) of MRI units before and after project completion or (ii) an equipment change other than a  
187 change in the magnet that involves a capital expenditure of \$500,000 or more in any consecutive 24-  
188 month period or (iii) the renewal of a lease. The term does not include an upgrade of an existing MRI  
189 service or unit, and it does not include a host site that proposes to receive mobile MRI services from a  
190 different central service coordinator if the requirements of Section 3(5)(a)-(e), as applicable, have been  
191 met.

192 (pp) "RESEARCH SCAN" MEANS AN MRI SCAN ADMINISTERED UNDER A RESEARCH  
193 PROTOCOL APPROVED BY THE APPLICANT'S INSTITUTIONAL REVIEW BOARD.

194 (qq) "RE-SEDATED PATIENT" MEANS A PATIENT, EITHER PEDIATRIC OR ADULT, WHO FAILS  
195 THE INITIAL SEDATION DURING THE SCAN TIME AND MUST BE EXTRACTED FROM THE UNIT TO  
196 RESCUE THE PATIENT WITH ADDITIONAL SEDATION.

197 (rr) "Rural county" means a county not located in a metropolitan statistical area or micropolitan  
198 statistical areas as those terms are defined under the "standards for defining metropolitan and  
199 micropolitan statistical areas" by the statistical policy office of the office of information regulatory affairs of  
200 the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as  
201 shown in Appendix A.

202 (ss) "Sedated patient" means a patient that meets all of the following:

203 (i) whose level of consciousness is either conscious-sedation or a higher level of sedation, as  
204 defined by the American Association of Anesthesiologists, the American Academy of Pediatrics, the Joint  
205 Commission on the Accreditation of Health Care Organizations, or an equivalent definition.

206 (ii) who is monitored by mechanical devices while in the magnet.

207 (iii) who requires observation while in the magnet by personnel, other than employees routinely  
208 assigned to the MRI unit, who are trained in cardiopulmonary resuscitation (CPR).

209 (tt) "Site," for purposes of these standards, means

210 (i) in the case of a licensed hospital site, a location that is part of the licensed hospital site or a  
211 location that is contiguous to the licensed hospital site or

212 (ii) in the case of a location that is not a licensed hospital site, a location at the same address or a  
213 location that is contiguous to that address.

214 (uu) "SPECIAL NEEDS PATIENT" MEANS A NON-SEDATED PATIENT, EITHER PEDIATRIC OR  
215 ADULT, WITH ANY OF THE FOLLOWING CONDITIONS: DOWN SYNDROME, AUTISM, ATTENTION  
216 DEFICIT HYPERACTIVITY DISORDER (ADHD), DEVELOPMENTAL DELAY, MALFORMATION

SYNDROMES, HUNTER'S SYNDROME, MULTI-SYSTEM DISORDERS, PSYCHIATRIC DISORDERS,  
AND OTHER CONDITIONS THAT MAKE THE PATIENT UNABLE TO COMPLY WITH THE  
POSITIONAL REQUIREMENTS OF THE EXAM.

(VV) "Teaching facility," for purposes of these standards, means a licensed hospital site, or other location, that provides either fixed or mobile MRI services and at which residents or fellows of a training program in diagnostic radiology, that is approved by the Accreditation Council on Graduate Medical Education or American Osteopathic Association, are assigned.

(#VV) "Unadjusted MRI scan" means an MRI procedure performed on a single anatomical site as defined by the MRI database and that is not adjusted pursuant to the applicable provisions of Section 13.

(++XX) "Upgrade an existing MRI unit" means any equipment change that

(i) does not involve a change in, or replacement of, the magnet; does not result in an increase in the number of MRI units; or does not result in a change in the type of MRI unit (e.g., changing a mobile MRI unit to a fixed MRI unit); and

(ii) involves a capital expenditure of less than \$500,750,000 in any consecutive 24-month period.

(2) Terms defined in the Code have the same meanings when used in these standards.

### Section 3. Requirements for approval of applicants proposing to initiate an MRI service or mobile MRI host site

Sec. 3. (1) An applicant proposing to initiate a fixed MRI service shall demonstrate that 6,000 available MRI adjusted procedures, from within the same planning area as the proposed service/unit, per proposed unit result from application of the methodology in Section 15 of these standards.

(2)(a) An applicant proposing to initiate a mobile MRI service that involves beginning operation of a mobile MRI unit shall demonstrate that a minimum of 5,500 available MRI adjusted procedures, from within the same planning area as the proposed service/unit, per proposed unit result from application of the methodology in Section 15 of these standards.

(b) The applicant, whether the central service coordinator or the host site, must demonstrate that a minimum of 600 available MRI adjusted procedures, from within the same planning area as the proposed service/unit, result from the application of the methodology in Section 15 of these standards, for each proposed host site that

(i) is not located in a rural or micropolitan statistical area county and

(ii) has not received any mobile MRI service within the most recent 12-month period as of the date an application is submitted to the Department.

(c) The applicant, whether the central service coordinator or the host site, must demonstrate that a minimum of 400 available MRI adjusted procedures, from within the same planning area as the proposed service/unit, result from the application of the methodology in Section 15 of these standards for each proposed host site that

(i) is located in a rural or micropolitan statistical area county and

(ii) has not received any mobile MRI service within the most recent 12-month period as of the date an application is submitted to the Department.

(3)(a) An applicant, whether the central service coordinator or a proposed host site, proposing to initiate a mobile MRI host site not in a rural or micropolitan statistical area county, that is to be part of an existing mobile MRI service, must demonstrate that at least 600 available MRI adjusted procedures, from within the same planning area as the proposed service/unit, result from the application of the methodology in Section 15 of these standards for that host site.

(b) An applicant, whether the central service coordinator or a proposed host site, proposing to initiate a mobile MRI host site in a rural or micropolitan statistical area county, that is to be part of an existing mobile MRI service, must demonstrate that at least 400 available MRI adjusted procedures, from within the same planning area as the proposed service/unit, result from the application of the methodology in Section 15 of these standards for that host site.

(4) An applicant that meets all of the following requirements shall not be required to be in



compliance with subsection (1):

- (a) The applicant is proposing to initiate a fixed MRI service.
- (b) The applicant is currently a host site being served by one or more mobile MRI units.
- (c) The applicant has received, in aggregate, the following:
  - (i) at least 6,000 MRI adjusted procedures within the most recent 12-month period for which data, verifiable by the Department, are available or
  - (ii) at least 4,000 MRI adjusted procedures within the most recent 12-month period for which data, verifiable by the Department, are available, and the applicant meets all of the following:
    - (A) is located in a county that has no fixed MRI machines that are pending, approved by the Department, or operational at the time the application is deemed submitted;
    - (B) the nearest fixed MRI machine is located more than 15 radius miles from the application site;
    - (C) the applicant is a nonprofit licensed hospital site;
    - (D) the applicant certifies in its CON application, by providing a governing body resolution, that the board of trustees of the facility has performed a due diligence investigation and has determined that the fixed MRI service will be economically viable to ensure provision of safe and appropriate patient access within the community hospital setting.
- (d) All of the MRI adjusted procedures provided at the applicant's approved site in the most recent 12-month period, referenced in (c) above, by each mobile MRI service/unit from which any of the MRI adjusted procedures are being utilized to meet the minimum 6,000 or 4,000 MRI adjusted procedures shall be utilized to meet the requirements of (c). [For example: If mobile network 19 provided 4,000 adjusted procedures, network 21 provided 2,100, and network 18 provided 1,000, all of the adjusted procedures from network 19 and 21 must be used (i.e., 6,100) but the 1,000 adjusted procedures from network 18 do not need to be used to meet the 6,000 minimum.]
- (e) The applicant shall install the fixed MRI unit at the same site as the existing approved host site.
- (5) Initiation of a mobile MRI host site does not include the provision of mobile MRI services at a host site if the applicant, whether the host site or the central service coordinator, demonstrates or provides each of the following, as applicable:
  - (a) The host site has received mobile MRI services from an existing mobile MRI unit within the most recent 12-month period as of the date an application is submitted to the Department.
  - (b) The addition of a host site to a mobile MRI unit will not increase the number of MRI units operated by the central service coordinator or by any other person.
  - (c) Notification to the Department of the addition of a host site prior to the provision of MRI services by that mobile MRI unit in accordance with (d).
  - (d) A signed certification, on a form provided by the Department, whereby each host site for each mobile MRI unit has agreed and assured that it will provide MRI services in accordance with the terms for approval set forth in Section 12 of these standards, as applicable. The central service coordinator also shall identify all current host sites, on this form, that are served by the mobile route as of the date of the signed certification or are committed in writing to be served by the mobile route.
  - (e) The central service coordinator requires, as a condition of any contract with a host site, compliance with the requirements of these standards by that host site, and the central service coordinator assures compliance, by that host site, as a condition of the CON issued to the central service coordinator.

#### **Section 4. Requirements for approval of an application proposing to expand an existing MRI service**

Sec. 4. (1) An applicant proposing to expand an **EXISTING** fixed MRI service shall demonstrate that its existing fixed MRI units ~~(excluding MRI units approved pursuant to Section 10)~~ have performed at least an average of 11,000 adjusted procedures for each fixed unit, **EXCLUDING EXISTING MRI UNITS APPROVED PURSUANT TO SECTION 10 WHICH SHALL HAVE PERFORMED AT LEAST AN AVERAGE OF 3,500 ADJUSTED PROCEDURES FOR EACH FIXED UNIT**, based on the application of the methodology in Section 13 and as documented in accordance with Section 14 of these standards.

**(A) THE ADDITIONAL UNIT SHALL BE LOCATED AT THE SAME SITE UNLESS THE**

325 **REQUIREMENTS OF SECTION 7(2) HAVE BEEN MET.**

326  
327 (2) An applicant proposing to expand a **N EXISTING** mobile MRI service shall demonstrate that  
328 4,000 available MRI adjusted procedures, from within the same planning area as the proposed  
329 ~~service/unit~~, per proposed additional unit result from application of the methodology in Section 15 of these  
330 standards.

331  
332 (3) An applicant proposing to expand a **N EXISTING** mobile MRI service must provide a copy of the  
333 existing or revised contracts between the central service coordinator and each host site(s) that includes  
334 the same stipulations as specified in Section 6(2).  
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336 **Section 5. Requirements for approval of an applicant proposing to replace an existing MRI unit**

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338 Sec. 5. An applicant proposing to replace an existing MRI unit shall demonstrate that the proposed  
339 project meets each of the following requirements:  
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341 (1) Within the most recent 12-month period for which data, verifiable by the Department, are  
342 available, at least the applicable minimum number of MRI adjusted procedures set forth in subdivision (a),  
343 (b), or (c) has been performed. In meeting this requirement, an applicant shall not include any  
344 procedures conducted by an MRI unit approved pursuant to Section 9(1).

345 (a) Each **EXISTING** mobile MRI unit ~~to be replaced~~ **ON THE NETWORK** has performed in excess  
346 of an average of 5,500 MRI adjusted procedures per MRI unit.

347 (b) Each **EXISTING** fixed MRI unit ~~to be replaced~~ **AT THE CURRENT SITE** has performed in  
348 excess of an average of 6,000 MRI adjusted procedures per MRI unit.

349 (c) ~~The EACH EXISTING~~ dedicated pediatric MRI unit ~~to be replaced~~ **AT THE CURRENT SITE** has  
350 performed in excess of 3,500 MRI adjusted procedures per MRI unit.  
351

352 (2) An applicant proposing to replace an **EXISTING** MRI unit that does not involve a renewal of a  
353 lease shall demonstrate that the MRI unit to be replaced is fully depreciated according to generally  
354 accepted accounting principles; the existing equipment clearly poses a threat to the safety of the public;  
355 or the proposed replacement equipment offers a significant technological improvement which enhances  
356 quality of care, increases efficiency, and reduces operating costs.  
357

358 (3) Equipment that is replaced shall be removed from service and disposed of or rendered  
359 considerably inoperable on or before the date that the replacement equipment becomes operational.  
360

361 (4) An applicant proposing to replace a **N EXISTING** mobile MRI unit must provide a copy of the  
362 existing or revised contracts between the central service coordinator and each host site(s) that includes  
363 the same stipulations as specified in Section 6(2).  
364

365 **(5) THE REPLACEMENT UNIT SHALL BE LOCATED AT THE SAME SITE UNLESS THE**  
366 **REQUIREMENTS OF SECTION 7(2) HAVE BEEN MET.**  
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368 **Section 6. Additional requirements for approval of an applicant proposing to initiate a mobile MRI**  
369 **service**

370  
371 Sec. 6. (1) An applicant proposing to initiate a mobile MRI service that involves beginning operation  
372 of a mobile MRI unit shall identify the proposed regular route schedule and the procedures for handling  
373 emergency situations.  
374

375 (2) An applicant proposing a mobile MRI service shall submit copies of all proposed contracts  
376 related to the mobile MRI service in the CON application submitted by the central service coordinator.  
377 The contract shall include at least the following:

(a) A signed certification, on a form provided by the Department, whereby each host site has agreed and assured that it will provide MRI services for each mobile MRI unit in accordance with the terms of approval set forth in Section 12 of these standards, as applicable. The central service coordinator also shall identify all current host sites, on this form, as of the date of the signed certification.

(b) A statement that requires compliance with the requirements of these standards by that host site and assures compliance, by that host site, as a condition of the CON issued to the central service coordinator.

(c) A signed agreement between the central service coordinator and the host site(s) that states that for any host site applying, at any time in the future, for a fixed MRI unit under Section 3(4), that the mobile services at the host site will not cease until the fixed unit is in operation or upon the request of the host site. Further, the applicant applying for the fixed MRI unit must stipulate in the application at the time it is submitted to the Department that it has notified all affected host sites as well as the central service coordinator at least six months prior to beginning operation of the fixed MRI unit.

## **Section 7. Requirements for approval of an applicant proposing to relocate an existing MRI service AND/OR MRI unit(s)**

Sec 7. (1) An applicant proposing to relocate an existing FIXED MRI service/ AND ITS unit(s) shall demonstrate that the proposed project meets all of the following:

(2A) The EXISTING MRI service/ AND ITS unit(s) to be relocated has been in operation for at least 36 months as of the date an application is submitted to the Department.

(3B) The proposed new site of the existing MRI service/ AND ITS unit(s) to be relocated is in the relocation zone.

(4C) The proposed project will not result in the replacement of the EXISTING MRI unit(s) to be relocated unless the applicant demonstrates that the requirements of Section 5, as applicable, also have been met.

(5D) The proposed project will not result in an increase of the number of MRI units operated by the EXISTING MRI service AT THE PROPOSED SITE UNLESS THE APPLICANT DEMONSTRATES THAT THE REQUIREMENTS OF SECTION 4, AS APPLICABLE, HAVE BEEN MET.

(6E) Each EXISTING MRI unit to be relocated performed at least the applicable minimum number of MRI adjusted procedures set forth in Section 12(1)(d)(i) of these standards based on the most recent 12-month period for which the Department has verifiable data.

(7F) The applicant agrees to operate the MRI service or AND ITS unit(s) in accordance with all applicable project delivery requirements set forth in Section 12 of these standards.

(2) AN APPLICANT PROPOSING TO RELOCATE A FIXED MRI UNIT OF AN EXISTING MRI SERVICE SHALL DEMONSTRATE THAT THE PROPOSED PROJECT MEETS ALL OF THE FOLLOWING:

(A) THE EXISTING MRI SERVICE FROM WHICH THE MRI UNIT(S) TO BE RELOCATED HAS BEEN IN OPERATION FOR AT LEAST 36 MONTHS AS OF THE DATE AN APPLICATION IS SUBMITTED TO THE DEPARTMENT.

(B) THE PROPOSED NEW SITE FOR THE MRI UNIT(S) TO BE RELOCATED IS IN THE RELOCATION ZONE.

(C) THE PROPOSED PROJECT WILL NOT RESULT IN THE REPLACEMENT OF THE MRI UNIT(S) TO BE RELOCATED UNLESS THE APPLICANT DEMONSTRATES THAT THE REQUIREMENTS OF SECTION 5, AS APPLICABLE, HAVE BEEN MET.

(D) THE PROPOSED PROJECT WILL NOT RESULT IN AN INCREASE OF THE NUMBER OF MRI UNITS OPERATED BY AN EXISTING MRI SERVICE AT THE PROPOSED SITE UNLESS THE APPLICANT DEMONSTRATES THAT THE REQUIREMENTS OF SECTION 4, AS APPLICABLE, HAVE BEEN MET.

(E) EACH EXISTING MRI UNIT TO BE RELOCATED PERFORMED AT LEAST THE APPLICABLE MINIMUM NUMBER OF MRI ADJUSTED PROCEDURES SET FORTH IN SECTION 12(1)(D)(I) OF THESE STANDARDS BASED ON THE MOST RECENT 12-MONTH PERIOD FOR WHICH THE DEPARTMENT HAS VERIFIABLE DATA.



(F) THE APPLICANT AGREES TO OPERATE THE MRI UNIT(S) AT THE PROPOSED SITE IN ACCORDANCE WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS SET FORTH IN SECTION 12 OF THESE STANDARDS.

(G) FOR VOLUME PURPOSES, THE NEW SITE SHALL REMAIN ASSOCIATED TO THE ORIGINAL SITE FOR A MINIMUM OF THREE YEARS.

(83) An applicant that meets all of the following requirements shall be exempt from subsection (3) RELOCATING WITHIN THE RELOCATION ZONE:

(a) The licensed hospital site to which the MRI service is to be relocated and the MRI service at the site from which the MRI service is to be relocated are owned by the same person as defined in Section 1106 of this public act or the same governmental entity.

(b) The licensed hospital site to which the MRI service is to be relocated is located within the planning area.

(c) As evidenced in the governing body resolution required in (e), the MRI service to be relocated shall cease at its current location within 24 months after the date the application receives a final decision of approval from the Department or upon the date the service becomes operational at the relocation site, whichever occurs first.

(d) The MRI service shall be relocated and shall be operational within 24 months after the date the application receives a final decision of approval from the Department or the CON to relocate the MRI service shall expire.

(e) The CON application includes a resolution of the applicant's governing body that commits to the provisions of (c) and (d).

(f) The relocation of the MRI service shall not result in the licensed hospital site having more than one fixed MRI unit.

#### **Section 8. Requirements for approval of an applicant proposing to acquire an existing MRI service/ OR AN EXISTING MRI unit(s)**

~~Sec 8-~~ (1) An applicant proposing to acquire an existing fixed or mobile MRI service/ AND ITS unit(s) shall demonstrate that the proposed project meets all of the following:

(4A) The project will not change the number of MRI units at the site of the MRI service being acquired unless the applicant demonstrates that the project is in compliance with the requirements of Section 3 or 4, as applicable.

(2B) The project will not result in the replacement of an MRI unit at the MRI service to be acquired unless the applicant demonstrates that the requirements of Section 5 also have been met.

(3C) The applicant agrees to operate the MRI service/ AND ITS unit(s) in accordance with all applicable project delivery requirements set forth in Section 12 of these standards.

(4D) For the first application proposing to acquire an existing fixed or mobile MRI service on or after July 1, 1997, the existing MRI service/ AND ITS unit(s) to be acquired shall not be required to be in compliance with the volume requirements applicable to a seller/lessor on the date the acquisition occurs. The MRI service shall be operating at the applicable volume requirements set forth in Section 12(1)(d)(i) of these standards in the second 12 months after the effective date of the acquisition, and annually thereafter.

(5E) For any application proposing to acquire an existing fixed or mobile MRI service/ AND ITS unit(s), except the first application approved pursuant to subsection (4D), an applicant shall be required to document that the MRI service/ AND ITS unit(s) to be acquired is operating in compliance with the volume requirements set forth in Section 12(1)(d)(i) of these standards applicable to an existing MRI service on the date the application is submitted to the Department.

(2) AN APPLICANT PROPOSING TO ACQUIRE AN EXISTING FIXED OR MOBILE MRI UNIT OF AN EXISTING MRI SERVICE SHALL DEMONSTRATE THAT THE PROPOSED PROJECT MEETS ALL OF THE FOLLOWING:

(A) THE APPLICANT SHALL DEMONSTRATE THAT THE PROJECT IS IN COMPLIANCE WITH THE REQUIREMENTS OF SECTION 3 OR 4, AS APPLICABLE.

(B) THE PROJECT WILL NOT RESULT IN THE REPLACEMENT OF AN MRI UNIT AT THE MRI SERVICE TO BE ACQUIRED UNLESS THE APPLICANT DEMONSTRATES THAT THE REQUIREMENTS OF SECTION 5 HAVE BEEN MET.

(C) THE APPLICANT AGREES TO OPERATE THE MRI UNIT(S) IN ACCORDANCE WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS SET FORTH IN SECTION 12 OF THESE STANDARDS.

#### **Section 9. Requirements for approval of an applicant proposing an MRI unit to be used exclusively for research**

Sec. 9. (1) An applicant proposing an MRI unit to be used exclusively for research shall demonstrate each of the following:

(a) The applicant operates a diagnostic radiology residency program approved by the Accreditation Council for Graduate Medical Education, the American Osteopathic Association, or an equivalent organization.

(b) The MRI unit shall operate under a protocol approved by the applicant's institutional review board.

(c) The applicant agrees to operate the unit in accordance with the terms of approval in Section 12(2).

(2) An applicant meeting the requirements of subsection (1) shall be exempt from meeting the requirements and terms of sections 3, 4, 5, 6, 7, 8, 12 [with the exception of 12(1)(d)(iii)], 14, and 15 of these standards.

#### **Section 10. Requirements for approval of an applicant proposing to establish dedicated pediatric MRI**

Sec. 10. (1) An applicant proposing to establish dedicated pediatric MRI shall demonstrate all of the following:

(a) The applicant shall have experienced at least 7,000 pediatric (< 18 years old) discharges (excluding normal newborns) in the most recent year of operation.

(b) The applicant shall have performed at least 5,000 pediatric (< 18 years old) surgeries in the most recent year of operation.

(c) The applicant shall have an active medical staff, at the time the application is submitted to the department, that includes, but is not limited to, physicians who are fellowship-trained in the following pediatric specialties:

- (i) pediatric radiology (at least two)
- (ii) pediatric anesthesiology
- (iii) pediatric cardiology
- (iv) pediatric critical care
- (v) pediatric gastroenterology
- (vi) pediatric hematology/oncology
- (vii) pediatric neurology
- (viii) pediatric neurosurgery
- (ix) pediatric orthopedic surgery
- (x) pediatric pathology
- (xi) pediatric pulmonology
- (xii) pediatric surgery
- (xiii) neonatology

(d) The applicant shall have in operation the following pediatric specialty programs at the time the application is submitted to the Department:

- (i) pediatric bone marrow transplant program
- (ii) established pediatric sedation program
- (iii) pediatric open heart program

(2) An applicant meeting the requirements of subsection (1) shall be exempt from meeting the requirements of Section 4, of these standards.

## Section 11. Requirements for approval -- all applicants

Sec. 11. An applicant shall provide verification of Medicaid participation at the time the application is submitted to the Department. **AN APPLICANT THAT IS INITIATING A NEW SERVICE OR IS A NEW PROVIDER NOT CURRENTLY ENROLLED IN MEDICAID SHALL PROVIDE A SIGNED AFFIDAVIT STATING THAT PROOF OF MEDICAID PARTICIPATION WILL BE PROVIDED TO THE DEPARTMENT WITHIN SIX (6) MONTHS FROM THE OFFERING OF SERVICES IF A CON IS APPROVED.** If the required documentation is not submitted with the application on the designated application date, the application will be deemed filed on the first applicable designated application date after all required documentation is received by the Department.

## Section 12. Project delivery requirements--terms of approval

Sec. 12. (1) An applicant shall agree that, if approved, ~~the services provided by the MRI unit~~ **SERVICES**, whether fixed or mobile, shall be delivered and maintained in compliance with the following terms of CON approval **FOR EACH GEOGRAPHICAL LOCATION WHERE THE APPLICANT OPERATES AN MRI UNIT:**

- (a) Compliance with these standards.
- (b) Compliance with applicable safety and operating standards for the specific MRI unit approved.
- (c) Compliance with the following quality assurance standards:
  - (i) An applicant shall develop and maintain policies and procedures that establish protocols for the following system performance measures. The protocols shall establish the required benchmarks; identify the testing interval, which shall be at least quarterly; and identify the MRI staff person responsible for testing the system performance measures.
    - (A) Signal-to-noise ratio.
    - (B) Spatial resolution.
    - (C) Slice thickness, location, and separation.
    - (D) Spatial linearity.
    - (E) Field homogeneity and drift.
    - (F) System calibration and stability.
    - (G) Cryogen level and boiloff rate.
    - (H) Radio frequency power monitor.
    - (I) Hard copy image quality.

In addition to the designated staff person, the system performance measures in subdivisions (A) through (F) and (H) also shall be evaluated by an appropriately trained MRI physicist or engineer. The physicist/engineer shall conduct tests of these system performance measures when the MRI unit begins to operate, and annually thereafter. The purpose of the physicist/engineer test shall be to certify to the Department that the MRI unit meets or exceeds all of the system performance specifications of the manufacturer of the MRI unit in effect for that MRI unit at the time of installation or most recent upgrade. The physicist/engineer shall make available for review the periodic system performance measures test data established in this subsection.

(ii) An applicant shall develop and maintain policies, procedures, and protocols for assuring the functionality of each of the following MRI accessories. The protocols shall establish the required benchmarks, identify the testing interval for each accessory, and identify the staff person responsible for testing the system performance measures.

- (A) All surface coils.
- (B) Positioning devices.
- (C) Physiologic triggering/monitoring equipment.
- (D) Patient communication devices.
- (E) Scan table position indicator and drives.

- 594 (F) Data network including storage and retrieval.
- 595 (G) Emergency rundown/shutdown units.
- 596 (H) Hard copy devices.
- 597 (iii) An applicant shall develop and maintain policies and procedures that establish protocols for
- 598 assuring the effectiveness of operation and the safety of the general public, patients, and staff in the MRI
- 599 service. Each of the following must be included and the staff person responsible for development and
- 600 enforcement of these policies shall be indicated.
- 601 (A) Access to the MRI service.
- 602 (B) Access to the MRI scan room.
- 603 (C) Patient safety clearance before imaging and safety during imaging.
- 604 (D) Adverse bioeffects, including
- 605 (1) acoustic hazard.
- 606 (2) radio frequency burn hazard.
- 607 (3) specific absorption rates.
- 608 (4) peripheral nerve stimulation.
- 609 (5) pregnancy.
- 610 (6) magnet quench hazard.
- 611 (E) Sedation.
- 612 (F) Contrast administration.
- 613 (G) Treatment of adverse reactions to contrast.
- 614 (H) Patient monitoring for sedation, anesthesia, and unstable patients.
- 615 (I) Patient resuscitation, management of emergencies, maintenance of cardiopulmonary
- 616 resuscitation equipment, and certification requirements for personnel for either basic or advanced
- 617 cardiopulmonary resuscitation.
- 618 (J) Screening for metallic implants, pacemakers, and metallic foreign bodies, as well as a list of
- 619 contraindications.
- 620 (K) Mechanism for consultation regarding difficult cases.
- 621 (L) Pulse sequence protocols for specific indications.
- 622 (M) Institutional review board policies relating to non-FDA approved pulse sequences or
- 623 investigational procedures.
- 624 (N) Staff inservice regarding subdivisions (A) through (M).
- 625 (iv) An applicant shall establish a schedule for preventive maintenance for the MRI unit.
- 626 (v) An applicant shall maintain records of the results of the periodic test data required by
- 627 subdivisions (i) and (ii), including the results of the tests performed by the MRI physicist/engineer required
- 628 in subdivision (i). An applicant, upon request, shall submit annually to the Department a report of the test
- 629 data results and evidence of compliance with the applicable project delivery requirements.
- 630 (vi) An applicant shall provide documentation identifying the specific individuals that form the MRI
- 631 team. At a minimum, the MRI team shall consist of the following professionals:
- 632 (A) An MRI team leader who shall be responsible for
- 633 (1) developing criteria for procedure performance.
- 634 (2) developing protocols for procedure performance.
- 635 (3) developing a clinical data base for utilization review and quality assurance purposes.
- 636 (4) transmitting requested data to the Department.
- 637 (5) screening of patients to assure appropriate utilization of the MRI service.
- 638 (6) taking and interpretation of scans.
- 639 (7) coordinating MRI activity at MRI host sites for a mobile MRI unit.
- 640 (8) identifying and correcting MRI image quality deficiencies.
- 641 (B) Physicians who shall be responsible for screening of patients to assure appropriate utilization
- 642 of the MRI service and taking and interpretation of scans. At least one of these physicians shall be a
- 643 board-certified radiologist.
- 644 (C) An appropriately trained MRI technician who shall be responsible for taking an MRI scan.
- 645 (D) An MRI physicist/engineer available as a team member on a full-time, part-time, or contractual
- 646 basis. An MRI physicist/engineer shall be responsible for at least the following:
- 647 (1) providing technical specifications for new equipment and assistance in equipment procurement.

648 (2) performing or validating technical performance for system acceptance.

649 (3) establishing preventive maintenance schedules and quality assurance test procedures and  
650 recording and reviewing preventive maintenance and quality assurance data.

651 (4) facilitating the repair of acute system malfunctions.

652 (5) training personnel in the MRI service with respect to the technical aspects of MRI scanning and  
653 patient and staff safety.

654 (6) assisting in designing and optimizing clinical imaging procedures.

655 (E) System maintenance personnel who shall be responsible for calibrating the MRI system and  
656 preventive maintenance at regularly scheduled intervals and who shall compile and submit quality control  
657 data to the MRI team leader.

658 (vii) An applicant shall document that the MRI team members have the following qualifications:

659 (A) The MRI team leader is a board-certified or board-eligible radiologist, or other physician trained  
660 in MRI, who spends greater than 75 percent of his or her professional time in multiple anatomic site  
661 medical imaging. The MRI team leader also shall demonstrate that he or she meets the requirements set  
662 forth in subsection (B) for a physician who interprets MRI images.

663 (B) Each physician credentialed to interpret MRI scans meets the requirements of each of the  
664 following:

665 (1) The physician is licensed to practice medicine in the State of Michigan.

666 (2) The physician has had at least 60 hours of training in MRI physics, MRI safety, and MRI  
667 instrumentation in a program that is part of an imaging program accredited by the Accreditation Council  
668 for Graduate Medical Education or the American Osteopathic Association, and the physician meets the  
669 requirements of subdivision (i), (ii), or (iii):

670 (i) Board certification by the American Board of Radiology, the American Osteopathic Board of  
671 Radiology, or the Royal College of Physicians and Surgeons of Canada. If the diagnostic radiology  
672 program completed by a physician in order to become board certified did not include at least two months  
673 of MRI training, that physician shall document that he or she has had the equivalent of two months of  
674 postgraduate training in clinical MRI imaging at an institution which has a radiology program accredited  
675 by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association.

676 (ii) Formal training by an imaging program(s), accredited by the Accreditation Council for Graduate  
677 Medical Education or the American Osteopathic Association, that included two years of training in cross-  
678 sectional imaging and six months training in organ-specific imaging areas.

679 (iii) A practice in which at least one-third of total professional time, based on a full-time clinical  
680 practice during the most recent 5-year period, has been the primary interpretation of MR imaging.

681 (3) The physician has completed and will complete a minimum of 40 hours every two years of  
682 Category in Continuing Medical Education credits in topics directly involving MR imaging.

683 (4) The physician interprets, as the primary interpreting physician, at least 250 unadjusted MRI  
684 scans annually.

685 (C) An MRI technologist who is registered by the American Registry of Radiologic Technicians OR  
686 BY THE AMERICAN REGISTRY OF MAGNETIC RESONANCE IMAGING TECHNOLOGISTS (ARMRIT)  
687 and has, or will have within 36 months of the effective date of these standards or the date a technologist  
688 is employed by an MRI service, whichever is later, special certification in MRI. If a technologist does not  
689 have special certification in MRI within either of the 3-year periods of time, all continuing education  
690 requirements shall be in the area of MRI services.

691 (D) An applicant shall document that an MRI physicist/engineer is appropriately qualified. For  
692 purposes of evaluating this subdivision, the Department shall consider it prima facie evidence as to the  
693 qualifications of the physicist/engineer if the physicist/engineer is certified as a medical physicist by the  
694 American Board of Radiology, the American Board of Medical Physics, or the American Board of Science  
695 in Nuclear Medicine. However, the applicant may submit and the Department may accept other evidence  
696 that an MRI physicist/engineer is qualified appropriately.

697 (E) An applicant shall document that system maintenance personnel are qualified on the basis of  
698 training and experience to perform the calibration, preventive maintenance, and quality control functions  
699 on the specific MRI unit approved.

700 (viii) The applicant shall have, within the MRI unit/service, equipment and supplies to handle clinical  
701 emergencies that might occur in the unit. MRI service staff will be trained in CPR and other appropriate



emergency interventions. A physician shall be on-site, in, or immediately available to the MRI unit at all times when patients are undergoing scans.

(ix) In addition to all other applicable terms of approval, each mobile MRI unit shall have an operations committee with members representing each host site, the central service coordinator, and the medical director. This committee shall oversee the effective and efficient use of the MRI unit, establish the normal route schedule, identify the process by which changes shall be made to the schedule, develop procedures for handling emergency situations, and review the ongoing operations of the mobile MRI unit on at least a quarterly basis.

(X) An applicant shall participate in Medicaid at least 12 consecutive months within the first two years of operation and continue to participate annually thereafter.

(d) Compliance with the following terms of approval, as applicable:

(i) MRI units shall be operating at a minimum average annual level of utilization during the second 12 months of operation, and annually thereafter, of 6,000 actual MRI adjusted procedures per unit for fixed MRI services, 5,500 actual MRI adjusted procedures per unit for mobile MRI services, and a total of 3,500 MRI adjusted procedures per unit for dedicated pediatric MRI. Each mobile host site in a rural or micropolitan statistical area county shall have provided at least a total of 400 adjusted procedures during its second 12 months of operation, and annually thereafter, from all mobile units providing services to the site. Each mobile host site not in a rural or micropolitan statistical area county shall have provided at least a total of 600 adjusted procedures during its second 12 months of operation and annually thereafter, from all mobile units providing services to the site. In meeting these requirements, an applicant shall not include any MRI adjusted procedures performed on an MRI unit used exclusively for research and approved pursuant to Section 9(1).

(ii) The applicant, to assure that the MRI unit will be utilized by all segments of the Michigan population, shall

(A) provide magnetic resonance services to all individuals based on the clinical indications of need for the service and not on ability to pay or source of payment.

(B) maintain information by source of payment to indicate the volume of care from each source provided annually.

Compliance with selective contracting requirements shall not be construed as a violation of this term.

(iii) The applicant shall participate in a data collection network established and administered by the Department or its designee. The data may include, but is not limited to annual budget and cost information, operating schedules, throughout schedules, demographic and diagnostic information, and the volume of care provided to patients from all payor sources, as well as other data requested by the Department or its designee and approved by the Commission. The applicant shall provide the required data in a format established by the Department and in a mutually agreed upon media no later than 30 days following the last day of the quarter for which data are being reported to the Department. An applicant shall be considered in violation of this term of approval if the required data are not submitted to the Department within 30 days following the last day of the quarter for which data are being reported. However, the Department shall allow an applicant up to an additional 60 days to submit the required data if reasonable efforts are made by an applicant to provide the required data. The Department may elect to verify the data through on-site review of appropriate records. Data for an MRI unit approved pursuant to Section 9(1) or Section 10 shall be reported separately.

(iv) The operation of and referral of patients to the MRI unit shall be in conformance with 1978 PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

(e)(i) The applicant shall provide the Department with a notice stating the first date on which the MRI unit became operational, and such notice shall be submitted to the Department consistent with applicable statute and promulgated rules.

(ii) An applicant who is a central service coordinator shall notify the Department of any additions, deletions, or changes in the host sites of each approved mobile MRI unit within 10 days after the change(s) in host sites is made.

(2) An applicant for an MRI unit under Section 9(1) shall agree that the services provided by the

MRI unit approved pursuant to Section 9(1) shall be delivered in compliance with the following terms of CON approval:

(a) The capital and operating costs relating to the research use of the MRI unit approved pursuant to Section 9(1) shall be charged only to a specific research account(s) and not to any patient or third-party payor.

(b) The MRI unit approved pursuant to Section 9(1) shall not be used for any purposes other than as approved by the institutional review board unless the applicant has obtained CON approval for the MRI unit pursuant to Part 222 and these standards, other than Section 9.

(3) The agreements and assurances required by this section shall be in the form of a certification authorized by the owner or governing body of the applicant.

(4) An applicant approved to initiate a fixed MRI service pursuant to Section 3(4) of these standards shall cease operation as a host site and not become a host site for at least 12 months from the date the fixed service ~~/AND ITS~~ unit becomes operational.

### Section 13. MRI procedure adjustments

Sec. 13. (1) The Department shall apply the following formula, as applicable, to determine the number of MRI adjusted procedures that are performed by an existing MRI service or unit:

(a) The base value for each MRI procedure is 1.0.

(b) For each MRI visit involving a pediatric patient, 0.25 shall be added to the base value.

(c) For each MRI visit involving an inpatient, 0.50 shall be added to the base value.

(d) For each MRI procedure performed on a sedated patient, 0.75 shall be added to the base value.

~~(e)~~ FOR EACH MRI PROCEDURE PERFORMED ON A RE-SEDATED PATIENT, 0.25 SHALL BE ADDED TO THE BASE VALUE.

~~(f)~~ FOR EACH MRI PROCEDURE PERFORMED ON A SPECIAL NEEDS PATIENT, 0.25 SHALL BE ADDED TO THE BASE VALUE.

~~(g)~~ FOR EACH MRI VISIT THAT INVOLVES BOTH A CLINICAL AND RESEARCH SCAN ON A SINGLE PATIENT IN A SINGLE VISIT, 0.25 SHALL BE ADDED TO THE BASE VALUE.

~~(h)~~ For each contrast MRI procedure performed after use of a contrast agent, and not involving a procedure before use of a contrast agent, 0.35 shall be added to the base value.

~~(i)~~ For each contrast MRI procedure involving a procedure before and after use of a contrast agent, 1.0 shall be added to the base value.

~~(g)~~ For each MRI procedure performed at a teaching facility, 0.15 shall be added to the base value.

~~(h)~~ The results of subsections (a) through (g) shall be summed, and that sum shall represent an MRI adjusted procedure.

(2) The Department shall apply not more than one of the adjustment factors set forth in this subsection, as applicable, to the number of MRI procedures adjusted in accordance with the applicable provisions of subsection (1) that are performed by an existing MRI service or unit.

(a) For a site located in a rural or micropolitan statistical area county, or for the November 1, 2005 MRI Service Utilization List, a county designated as "rural" as that term was defined under the "standards for defining metropolitan areas in the 1990s" by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 55 F.R. p 12154 (March 30, 1990), the number of MRI adjusted procedures shall be multiplied by a factor of 1.4.

(b) For a mobile MRI unit that serves hospitals and other host sites located in rural, micropolitan statistical area, and metropolitan statistical area counties, the number of MRI adjusted procedures for a site located in a rural or micropolitan statistical area county, or for the November 1, 2005 MRI Service Utilization List, a county designated as "rural" as that term was defined under the "standards for defining metropolitan areas in the 1990s" by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 55 F.R. p 12154 (March 30, 1990), shall be multiplied by a factor of 1.4 and for a site located in a metropolitan statistical area county, the number of

MRI adjusted procedures shall be multiplied by a factor of 1.0.

(c) For a mobile MRI unit that serves only sites located in rural or micropolitan statistical area counties, or for the November 1, 2005 MRI Service Utilization List, a county designated as "rural" as that term was defined under the "standards for defining metropolitan areas in the 1990s" by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 55 F.R. p 12154 (March 30, 1990), the number of MRI adjusted procedures shall be multiplied by a factor of 2.0.

(d) For a mobile MRI unit that serves only sites located in a health service area with one or fewer fixed MRI units and one or fewer mobile MRI units, the number of MRI adjusted procedures shall be multiplied by a factor of 3.5.

(e) Subsection (2) shall not apply to an application proposing a subsequent fixed MRI unit (second, third, etc.) at the same site.

(3) The number of MRI adjusted procedures performed by an existing MRI service is the sum of the results of subsections (1) and (2).

#### **Section 14. Documentation of actual utilization**

Sec. 14. Documentation of the number of MRI procedures performed by an MRI unit shall be substantiated by the Department utilizing data submitted by the applicant in a format and media specified by the Department and as verified for the 12-month period reported on the most recently published "Available MRI Adjusted Procedures List" as of the date an application is deemed complete by the Department. The number of MRI procedures actually performed shall be documented by procedure records and not by application of the methodology required in Section 15. The Department may elect to verify the data through on-site review of appropriate records.

#### **Section 15. Methodology for computing the number of available MRI adjusted procedures**

Sec. 15. (1) The number of available MRI adjusted procedures required pursuant to Section 3 or 4(2) of these standards shall be computed in accordance with the methodology set forth in this section. In applying the methodology, the following steps shall be taken in sequence, and data for the 12-month period reported on the most recently published "Available MRI Adjusted Procedures List," as of the date an application is deemed complete by the Department, shall be used:

(a) Identify the number of actual MRI adjusted procedures performed by each existing MRI service as determined pursuant to Section 13.

(i) For purposes of computing actual MRI adjusted procedures, MRI adjusted procedures performed on MRI units used exclusively for research and approved pursuant to Section 9(1) and dedicated pediatric MRI approved pursuant to Section 10 shall be excluded.

(ii) For purposes of computing actual MRI adjusted procedures, the MRI adjusted procedures, from the host site **ROUTES** utilized to meet the requirements of Section 3(4)(d), shall be excluded beginning at the time the application is ~~deemed complete~~**SUBMITTED** and for three years from the date the fixed MRI unit becomes operational.

(iii) For purposes of computing actual MRI adjusted procedures, the MRI adjusted procedures utilized to meet the requirements of Section 4(1) shall be reduced by 8,000 and shall be excluded beginning at the time the application is ~~deemed complete~~**SUBMITTED** and for three years from the date the fixed MRI unit becomes operational.

(b) Identify the number of available MRI adjusted procedures, if any, for each existing MRI service as determined pursuant to Section 2(1)(c).

(c) Determine the number of available MRI adjusted procedures that each referring doctor may commit from each service to an application in accordance with the following:

(i) Divide the number of available MRI adjusted procedures identified in subsection (b) for each service by the number of actual MRI adjusted procedures identified in subsection (a) for that existing MRI service.

(ii) For each doctor referring to that existing service, multiply the number of actual MRI adjusted

procedures that the referring doctor made to the existing MRI service by the applicable proportion obtained by the calculation in subdivision (c)(i).

(A) For each doctor, subtract any available adjusted procedures previously committed. The total for each doctor cannot be less than zero.

(B) The total number of available adjusted procedures for that service shall be the sum of the results of (A) above.

(iii) For each MRI service, the available MRI adjusted procedures resulting from the calculation in (ii) above shall be sorted in descending order by the available MRI adjusted procedures for each doctor. Then any duplicate values shall be sorted in descending order by the doctors' license numbers (last 6 digits only).

(iv) Using the data produced in iii above, sum the number of available adjusted procedures in descending order until the summation equals at least 75 percent of the total available adjusted procedures. This summation shall include the minimum number of doctors necessary to reach the 75 percent level.

(v) For the doctors representing 75 percent of the total available adjusted procedures in (iv) above, sum the available adjusted procedures.

(vi) For the doctors used in subsection (v) above, divide the total number of available adjusted procedures identified in (B) above by the sum of those available adjusted procedures produced in (v) above.

(vii) For only those doctors identified in (v) above, multiply the result of (vi) above by the available adjusted procedures calculated in (c)(ii)(A) above.

(viii) The result shall be the "Available MRI Adjusted Procedures List."

(2) After publication of the "Available MRI Adjusted Procedures List" resulting from (i) above, the data shall be updated to account for a) doctor commitments of available MRI adjusted procedures in subsequent MRI CON applications and b) MRI adjusted procedures used in subsequent MRI CON applications received in which applicants apply for fixed MRI services pursuant to Section 3(4).

#### **Section 16. Procedures and requirements for commitments of available MRI adjusted procedures**

Sec. 16. (1) If one or more host sites on a mobile MRI service are located within the planning area of the proposed site, the applicant may access available MRI adjusted procedures from the entire mobile MRI service.

(2)(a) At the time the application is submitted to the Department, the applicant shall submit a signed data commitment, on a form provided by the Department in response to the applicant's letter of intent or at the applicant's discretion, on a more current form subsequently provided by the Department, for each doctor committing available MRI adjusted procedures to that application for a new or additional MRI unit pursuant to Section 3 or Section 4(2), respectively.

(b) An applicant also shall submit, at the time the application is filed with the Department, a computer file that lists, for each MRI service from which data are being committed to the same application, the name and license number of each doctor for whom a signed AND DATED data commitment form is submitted.

(i) The computer file shall be provided to the Department on mutually agreed upon media and in a format prescribed by the Department.

(ii) If the doctor commitments submitted on the departmental forms do not agree with the data on the computer file, the applicant shall be allowed to correct only the computer file data WHICH INCLUDES ADDING PHYSICIAN COMMITMENTS THAT WERE SUBMITTED AT THE TIME OF APPLICATION.

(c) If the required documentation for the doctor commitments submitted under this subsection is not submitted with the application on the designated application date, the application will be deemed filed on the first applicable designated application date after all required documentation is received by the Department.

(3) The Department shall consider a data commitment, on a form provided by the Department in

915 response to the applicant's letter of intent or at the applicant's discretion, on a more current form  
916 subsequently provided by the Department, submitted by the applicant in support of its application, that  
917 meets the requirements of each of the following, as applicable:

918 (a) A committing doctor certifies that 100% of his or her available MRI adjusted procedures for  
919 each specified MRI service, calculated pursuant to Section 15, is being committed and specifies the CON  
920 application number, for the new fixed or mobile MRI unit or for the additional mobile MRI unit proposed to  
921 be located within the planning area, to which the data commitment is made. A doctor shall not be  
922 required to commit available MRI adjusted procedures from all MRI services to which his or her patients  
923 are referred for MRI services but only from those MRI services specified by the doctor in the data  
924 commitment form provided by the Department and submitted by the applicant in support of its application.

925 (b) A committing doctor certifies that he or she does not have an ownership interest, either direct  
926 or indirect, in the applicant entity, except that this requirement shall not apply if the applicant entity is a  
927 group practice of which the committing doctor is a member.

928 (c) A committing doctor certifies that he or she has not been provided, or received a promise of  
929 being provided, a financial incentive to commit any of his or her available MRI adjusted procedures to the  
930 application.

931 (4)(a) The Department shall not consider a data commitment from a doctor for available MRI adjusted  
932 procedures from a specific MRI service if the available MRI adjusted procedures from that specific MRI  
933 service were used to support approval of an application for a new or additional MRI unit, pursuant to  
934 Section 3 or 4(2), respectively, for which a final decision to approve has been issued by the Director of  
935 the Department until either of the following occurs:

936 (i) The approved CON is withdrawn or expires.

937 (ii) The MRI service or unit to which the data were committed has been in operation for at least 36  
938 continuous months.

939 (b) The Department shall not consider a data commitment from a doctor for available MRI adjusted  
940 procedures from a specific MRI service if the available MRI adjusted procedures from that specific MRI  
941 service were used to support an application for a new fixed or mobile MRI unit or additional mobile MRI  
942 unit pursuant to Section 3 or 4(2), respectively, for which a final decision to disapprove was issued by the  
943 Director of the Department until either of the following occurs:

944 (i) A final decision to disapprove an application is issued by the Director and the applicant does  
945 not appeal that disapproval or

946 (ii) If an appeal was made, either that appeal is withdrawn by the applicant or the committing  
947 doctor withdraws his or her data commitment pursuant to the requirements of subsection (8).

948  
949 (5) The Department shall not consider a data commitment from a committing doctor for available  
950 MRI adjusted procedures from the same MRI service if that doctor has submitted a signed data  
951 commitment, on a form provided by Department, for more than one (1) application for which a final  
952 decision has not been issued by the Department. If the Department determines that a doctor has  
953 submitted a signed data commitment for the same available MRI adjusted procedures from the same MRI  
954 service to more than one CON application pending a final decision for a new fixed or mobile MRI unit or  
955 additional mobile MRI unit pursuant to Section 3 or 4(2), respectively, the Department shall,

956 (a) if the applications were filed on the same designated application date, notify all applicants,  
957 simultaneously and in writing, that one or more doctors have submitted data commitments for available  
958 MRI adjusted procedures from the same MRI service and that the doctors' data from the same MRI  
959 service shall not be considered in the review of any of the pending applications filed on the same  
960 designated application date until the doctor notifies the Department, in writing, of the one (1) application  
961 for which the data commitment shall be considered.

962 (b) if the applications were filed on different designated application dates, consider the data  
963 commitment submitted in the application filed on the earliest designated application date and shall notify,  
964 simultaneously in writing, all applicants of applications filed on designated application dates subsequent  
965 to the earliest date that one or more committing doctors have submitted data commitments for available  
966 MRI adjusted procedures from the same MRI service and that the doctors' data shall not be considered in  
967 the review of the application(s) filed on the subsequent designated application date(s).



(6) The Department shall not consider any data commitment submitted by an applicant after the date an application is deemed complete unless an applicant is notified by the Department, pursuant to subsection (5), that one or more committing doctors submitted data commitments for available MRI adjusted procedures from the same MRI service. If an applicant is notified that one or more doctors' data commitments will not be considered by the Department, the Department shall consider data commitments submitted after the date an application is deemed complete only to the extent necessary to replace the data commitments not being considered pursuant to subsection (5).

(7) In accordance with either of the following, the Department shall not consider a withdrawal of a signed data commitment

(a) during the 120-day period following the date on which the Department's review of an application commences.

(b) after a proposed decision to approve an application has been issued by the Department.

(8) The Department shall consider a withdrawal of a signed data commitment if a committing doctor submits a written notice to the Department, that specifies the CON application number and the specific MRI services for which a data commitment is being withdrawn, and if an applicant demonstrates that the requirements of subsection (7) also have been met.

#### **Section 17. Lists of MRI adjusted procedures published by the Department**

Sec. 17. (1) At a minimum, on or before May 1 and November 1 of each year, the Department shall publish the following lists:

(a) A list, known as the "MRI Service Utilization List," of all MRI services in Michigan that includes at least the following for each MRI service:

(i) The number of actual MRI adjusted procedures;

(ii) The number of available MRI adjusted procedures, if any; and

(iii) The number of MRI units, including whether each unit is a clinical unit or an MRI unit used exclusively for research.

(b) A list, known as the "Available MRI Adjusted Procedures List," that identifies each MRI service that has available MRI adjusted procedures and includes at least the following:

(i) The number of available MRI adjusted procedures;

(ii) The name, address, and license number of each referring doctor, identified in Section

4415(1)(c)(v), whose patients received MRI services at that MRI service; and

(iii) The number of available MRI adjusted procedures performed on patients referred by each referring doctor, identified in Section 15(1)(c)(v), and if any are committed to an MRI service. This number shall be calculated in accordance with the requirements of Section 15(1). A referring doctor may have fractional portions of available MRI adjusted procedures.

(c) For the lists published pursuant to subsections (a) or (b), the May 1 list will report 12 months of data from the previous January 1 through December 31 reporting period, and the November 1 list will report 12 months of data from the previous July 1 through June 30 reporting period. Copies of both lists shall be available upon request.

(d) The Department shall not be required to publish a list that sorts MRI database information by referring doctor, only by MRI service.

(2) When an MRI service begins to operate at a site at which MRI services previously were not provided, the Department shall include in the MRI database, data beginning with the second full quarter of operation of the new MRI service. Data from the start-up date to the start of the first full quarter will not be collected to allow a new MRI service sufficient time to develop its data reporting capability. Data from the first full quarter of operation will be submitted as test data but will not be reported in the lists published pursuant to this section.

(3) In publishing the lists pursuant to subsections (a) and (b), if an MRI service has not reported data in compliance with the requirements of Section 12(1)(d)(iii), the Department shall indicate on both lists that the MRI service is in violation of the requirements set forth in Section 12(1)(d)(iii), and no data

will be shown for that service on either list.

(4) In the case of an MRI service at which MRI services previously were not provided, the Department may use annualized data from at least a consecutive six-month period in publishing the lists pursuant to subsections (a) and (b).

**Section 18. Effect on prior CON Review Standards; Comparative reviews**

Sec. 18. (1) These CON review standards supersede and replace the CON Review Standards for Magnetic Resonance Imaging Services approved by the CON Commission on ~~May 11, 2004~~ JUNE 22, 2005 and effective ~~July 12, 2004~~ OCTOBER 17, 2005.

(2) Projects reviewed under these standards shall not be subject to comparative review.

**Section 19. Health Service Areas**

Sec. 19. Counties assigned to each of the health service areas are as follows:

HSA	COUNTIES
1	Livingston Macomb Wayne
2	Clinton Eaton
3	Barry Berrien Branch
4	Allegan Ionia Kent Lake
5	Genesee
6	Arenac Bay Clare Gladwin Gratiot
7	Alcona Alpena Antrim Benzie Charlevoix Cheboygan
8	Alger Baraga Chippewa Delta Dickinson
	Monroe Oakland
	Hillsdale Ingham
	Calhoun Cass Kalamazoo
	Mason Mecosta Montcalm Muskegon
	Lapeer
	Huron Iosco Isabella Midland Ogemaw
	Crawford Emmet Gd Traverse Kalkaska Leelanau Manistee
	Gogebic Houghton Iron Keweenaw Luce
	St. Clair Washtenaw
	Jackson Lenawee
	St. Joseph Van Buren
	Newaygo Oceana Osceola Ottawa
	Shiawassee
	Roscommon Saginaw Sanilac Tuscola
	Missaukee Montmorency Oscoda Otsego Presque Isle Wexford
	Mackinac Marquette Menominee Ontonagon Schoolcraft

**CON REVIEW STANDARDS  
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Rural Michigan counties are as follows:

Alcona	Hillsdale	Ogemaw
Alger	Huron	Ontonagon
Antrim	Iosco	Osceola
Arenac	Iron	Oscoda
Baraga	Lake	Otsego
Charlevoix	Luce	Presque Isle
Cheboygan	Mackinac	Roscommon
Clare	Manistee	Sanilac
Crawford	Mason	Schoolcraft
Emmet	Montcalm	Tuscola
Gladwin	Montmorency	
Gogebic	Oceana	

Micropolitan statistical area Michigan counties are as follows:

Allegan	Gratiot	Mecosta
Alpena	Houghton	Menominee
Benzie	Isabella	Midland
Branch	Kalkaska	Missaukee
Chippewa	Keweenaw	St. Joseph
Delta	Leelanau	Shiawassee
Dickinson	Lenawee	Wexford
Grand Traverse	Marquette	

Metropolitan statistical area Michigan counties are as follows:

Barry	Ionia	Newaygo
Bay	Jackson	Oakland
Berrien	Kalamazoo	Ottawa
Calhoun	Kent	Saginaw
Cass	Lapeer	St. Clair
Clinton	Livingston	Van Buren
Eaton	Macomb	Washtenaw
Genesee	Monroe	Wayne
Ingham	Muskegon	

Source:

65 F.R., p. 82238 (December 27, 2000)  
Statistical Policy Office  
Office of Information and Regulatory Affairs  
United States Office of Management and Budget